

EXHIBIT B

Declaration of Katherine Zeigler, Regional Administrator of the
West Tennessee Office for the Health Facilities Commission

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

STATES OF TENNESSEE, ALABAMA,)
ARKANSAS, GEORGIA, IDAHO, INDIANA,)
IOWA, LOUISIANA, MONTANA,)
NEBRASKA, NORTH DAKOTA, OHIO,)
SOUTH CAROLINA, SOUTH DAKOTA, and)
WEST VIRGINIA,)

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND)
HUMAN SERVICES; XAVIER BECERRA, in)
his official capacity as Secretary of Health and)
Human Services; and U.S. DEPARTMENT OF)
HEALTH AND HUMAN SERVICES OFFICE)
OF CIVIL RIGHTS,)

Defendants.

Civil Action No. 25-cv-00025

DECLARATION OF KATHERINE ZEIGLER

Pursuant to 28 U.S.C. § 1746, I, Katherine Zeigler, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as Regional Administrator of the West Tennessee Regional Office for the Health Facilities Commission ("HFC") of the State of Tennessee. HFC's mission is to protect patients and promote quality in healthcare facilities throughout Tennessee. To that end, HFC investigates complaints regarding patient safety and facility conditions to ensure compliance with federal, *see* 42 C.F.R. § 482.1, *et seq.*, and state standards, *see* Tenn. Code Ann. §§ 68-11-207, 68-11-210.

3. For example, HFC conducts certification and compliance surveys of health facilities that participate in Medicare to ensure the facility maintains compliance with conditions of program participation. *See* 42 C.F.R. § 489.53(a)(18). These surveys are often undertaken in response to a patient complaint regarding care or conditions at a particular facility. HFC must have “immediate access” to “provider or supplier” records and facilities “for the purpose of determining” compliance. *Id.* Failure to grant such access could result in the Centers for Medicare and Medicaid Services (“CMS”) “terminat[ing]” its agreement with the provider. *Id.* § 489.53(a).

4. In conducting surveys pursuant to state and federal law, HFC regularly requests provider records that contain protected health information (“PHI”) under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (“HIPAA”). These requests are most often directed to the facility under investigation, but sometimes it is necessary to request records from other providers along the patient-care chain to adequately investigate certain complaints. For example, if a patient complains that they suffered harm after being transferred to a new facility, it may be necessary to compare the patient records at prior facilities to track the diagnoses and care the patient received.

5. Because of their obligations under state and federal law, *see, e.g.*, Tenn. Code Ann. § 68-11-210 *et. seq.*; 42 C.F.R. § 489.53(a)(18), healthcare facilities in the past generally complied with survey requirements, including by providing requested records.

6. I am aware of the Department of Health and Human Services’ *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the “Final Rule”), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

7. The Final Rule is currently hindering HFC’s investigation of healthcare facilities.

8. For example, HFC recently received two complaints against a licensed psychiatric facility, including a complaint that one of the facility's patients received substandard care before being transferred to a regional hospital and dying shortly thereafter. HFC also received a complaint that a patient at a senior living facility suffered a fatal injury after being struck in the head by a ceiling tile. HFC commenced surveys pursuant to these complaints to determine whether the facilities were following state and federal standards to ensure the safety of other patients. As part of the surveys, HFC requested records from the hospitals who received the patients via emergency medical transport to the emergency room. Medical records are required to determine the patient's admitting diagnoses and condition.

9. These records are necessary to HFC's investigation because HFC received a complaint alleging harm to the patient within the psychiatric facility resulting in death. Without the requested records, HFC cannot know the patient's condition, diagnoses, or whether or not the complaint can even be verified or substantiated. Nor can HFC determine whether unsafe conditions led to a patient's death at the licensed senior living facility without access to her post-injury treatment records.

10. HFC has also commenced an investigation against a renal clinic pursuant to a complaint. As part of that investigation, HFC has sought medical records related to the care and treatments of the patient receiving dialysis within the facility.

11. To date, the facilities in these investigations have refused to provide HFC with the requested materials without an attestation required under the Final Rule.

12. HFC has not completed those attestations because such a requirement conflicts with HFC's authority to "immediate access" to those materials. 42 C.F.R. § 489.53(a)(18). Moreover, HFC generally does not and cannot know the ends of its investigation at the time it requests

information from a facility. Thus, HFC employees have declined to provide an attestation considering the Final Rule's vague and overbroad standards given the criminal liability attached to HIPAA.

13. The stalled investigations are dangerous to the safety and well-being of Tennessee residents. HFC's survey of the psychiatric and senior living facilities are predicated on a complaint that resulted in a patient's death. Because HFC was denied access to the requested records, it could not intervene immediately to address possibly deadly, substandard care or dangerous conditions. With the investigation on hold, HFC has not yet been able to resolve the definite cause of the patients' deaths.

14. In the case of the renal clinic, the target of the investigation has effectively blocked HFC's survey to address the complaint against the facility.

15. Delay also creates the possibility for spoliation of evidence. In past investigations, HFC has learned of investigatory targets altering records during a survey. And without immediate access to necessary patient records, health care facilities have greater opportunity to alter records to conceal misconduct. Moreover, immediate access to the facility itself is necessary to accurately assess the conditions at the time allegedly substandard care was rendered or the allegedly dangerous condition existed.

16. HFC's stalled investigations also undermine its role in surveying healthcare facilities pursuant to our agreement with CMS. To date, CMS has provided no definitive guidance on how to navigate our obligations under that agreement considering the Final Rule's new disclosure requirements. It is my understanding that CMS is currently coordinating with HHS's Office for Civil Rights to understand the Final Rule's interaction with CMS survey regulations.

17. In addition to stopping HFC's investigations, the Final Rule has imposed compliance costs, including needing to assess how, if possible, to comply with the rule's attestation requirement.

18. Thus, the Final Rule is complicating HFC's duty and ability to investigate healthcare facilities for violations of law and noncompliance. Because of the Final Rule, investigations that HFC is undertaking are consuming more resources than they did before the Final Rule's effective date. And the Final Rule is actively thwarting pressing investigations. For those reasons, the Final Rule is impacting the public health and safety of the State of Tennessee because it is delaying, impeding, and deterring viable investigations.

Date: 2/6/25

Kathy Zeigler
